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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
09/314,161	05/19/99	EISENBACH-SCHWARTZ	M	EIS-SCHWARTZ

EXAMINER	
BUNNER, B	
ART UNIT	PAPER NUMBER
1647	13

001444
BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON DC 20001-5303

HM12/0614

DATE MAILED: 06/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev.11/00)

1- File Copy

Office Action Summary	Application No. 09/314,161	Applicant(s) EISENBACH-SCHWARTZ ET AL.	
	Examiner Bridget E. Bunner	Art Unit 1647	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 April 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) *9-15, 17-18, and 20-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-37* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of Application, Amendments, and/or Claims

Applicant's election with traverse of Group I (claims 1-8, 16, and 19), drawn to a method for preventing or inhibiting neuronal degeneration in the central nervous system or peripheral nervous system comprising administering to an individual NS-specific activated T cells in Paper No. 12 (25 April 2001) is acknowledged. Applicants also elect without traverse spinal cord injury as the species of nervous system injury, glaucoma as the species of nervous system disease, and autologous T cells as the species of NS-specific activated T cell group in Paper No. 12 (25 April 2001). The traversal is on the ground(s) that Groups I and II (claims 1-3 and 9-16) are both directed to a method of using NS-specific activated T cells, whether "pre-activated" or activated *in vivo* by administering a NS-specific antigen or peptide. Applicants believe that there is no serious burden on the examiner to examine Groups I and II. It also asserted that an eight way restriction requirement is burdensome for the Applicants. This is not found persuasive because the claims of Groups I and II are drawn to different methods that require different ingredients, process steps, and endpoints. Groups I and II are different methods requiring different method steps, wherein each is not required, one for the other. For example, Group I requires search and consideration of sensitizing autologous T cells to a human NS-specific antigen *in vitro* and administering the T cells to a individual, which is not required by the other invention. Group II requires search and consideration of administering only an NS-specific antigen to an individual *in vivo*, which is not required by the other invention. Group I may possibly require a search of classes that overlap with classes of Group II, but there is no reason to believe that the searches would be co-extensive. Groups I and II each require divergent literature

searches. Further, while the added cost to the Applicants to file divisional applications is truly regretted, it is beyond the resources of the USPTO to permit examination of multiple inventions in a single application.

The requirement is still deemed proper and is therefore made FINAL.

Claims 9-15, 17-18, and 20-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 12 (25 April 2001).

Upon additional consideration, further restriction of the elected invention under 35 U.S.C. 121 is required.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I-A. Claims 1-8, 16, and 19, drawn to a method for preventing or inhibiting neuronal degeneration in the central nervous system comprising administering to an individual NS-specific activated T cells, classified in class 424, subclass 93.1.

II-B. Claims 1-8, 16, and 19, drawn to a method for preventing or inhibiting neuronal degeneration in the peripheral nervous system comprising administering to an individual NS-specific activated T cells, classified in class 424, subclass 93.1.

The inventions are distinct, each from the other because of the following reasons:

a. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to <u>different</u> methods, restriction is deemed to be proper because these methods constitute patentably distinct inventions for the following reasons. Inventions I-A and I-B are different methods because they require different ingredients, process steps, and endpoints. These inventions require different process steps to accomplish the use of NS-specific activated autologous T cells. Groups I-A and

I-B are different methods requiring different method steps, wherein each is not required, one for another. For example, Group I-A requires search and consideration of administration of NS-specific activated T cells to prevent or inhibit neuronal degeneration in the central nervous system, which is not require by the other invention. Group I-B requires search and consideration of administration of NS-specific activated T cells to prevent or inhibit neuronal degeneration in the peripheral nervous system, which is not required by the other invention.

2. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their different search and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

3. This application contains claims directed to the following patentably distinct species of the claimed invention:

A method for preventing or inhibiting neuronal degeneration in the central nervous system or peripheral nervous system for ameliorating the effects of :

i. injury
ii. disease

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 4-8 and 16 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

If Applicant selects Inventions I-II, one species from the group of nervous system defects must also be chosen to be fully responsive.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (703) 305-7148. The examiner can normally be reached on 8:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Kemmerer

Bridget E. Bunner
Art Unit 1647
June 11, 2001

ELIZABETH KEMMERER
PRIMARY EXAMINER